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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,059

Applicant(s)

BAKER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-87,89-99,101-104,110,111,113,114,121 and 131-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-74,76-87,89-95,97-99,101-104,110,111,113,114,121 and 131-133 is/are rejected.
- 7) ☒ Claim(s) 75 and 96 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 04/29/05. Claims 71-87, 89-99, 101-104, 110, 111, 113, 114, 121 and 131-133 are pending.

Claim Rejections - 35 USC § 102

1. The rejection of claims 71-74, 78, 79, 81-83, 89, 93-95, 104, 110, 111, 113 and 114 under 35 U.S.C. 102(e) as being anticipated by Baker, Jr. et al. (US 6,015,832) is withdrawn in light of applicants' persuasive argument that Baker's oil-in-water emulsion does not contain halogen containing compound.

2. The rejection of claims 71-74, 78-87, 90, 92-95, 97-99, 101-104, 113 and 114 under 35 U.S.C. 102(e) as being anticipated by Little-van den Hurk et al. (US 5,951,988) is withdrawn in light of the amendment to the claims that now require the phosphate based solvent to be organic phosphate based solvent and applicants' argument is persuasive that Little-van den Hurk does not disclose organic phosphate.

3. Claims 71-74, 76-78, 80-87, 90-95, 97-99, 101-104, 113 and 114 remain rejected under 35 U.S.C. 102(b) as being anticipated by Spitzer et al. (US 3,912,666).

Applicants argue that Spitzer does not disclose phosphate based solvent and thus does not teach each and every element of the claims. Applicants further state that Spitzer does not disclose the element of the amendment to claim 104, which recites that "said components are combined under conditions such that the said oil-in-water emulsion itself is antimicrobial."

4. Applicants' arguments filed 04/29/05 have been fully considered but they are not persuasive.

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Spitzer's composition may contain tricresyl phosphate (column 9, line 3), and although, Spitzer recognizes the tricresyl phosphate as a plasticizer, tricresyl phosphate is known solvent. Secondly, the tributyl phosphate is one of applicants' organic phosphate based solvent; and Dyker recognizes tributyl phosphate as a plasticizer (column 35, lines 13 and 14 of Dyker et al., US 6,127,364 teaching reference). It is respectfully noted that claim 71 is a composition claim and composition that is antimicrobial is an intended use of the composition. However, the composition of Spitzer contains cetyltrimethylammonium bromide, which has antiseptic and antimicrobial properties. The rejection is repeated below.

Spitzer discloses oil-in-water emulsion (abstract, column 6, line 34) that contains halogen compound such as vinyl chloride, methyl chloride, propellants and Freon and halogenated solvents (column 6, line 66 to column 7 line 9; column 8, lines 57-64), oil phase and aqueous phase (column 9, lines 31-42), surfactant such as sodium dodecyl sulfate, polyethylene glycol esters, cetyltrimethylammonium bromide (column 10, lines 16-67), ethyl alcohol or methyl alcohol or isopropyl alcohol or glycerol (column 11, lines 15-19). Spitzer's formulation may contain plasticizers such as tricresyl phosphate, butyl glycolate, citrate and phthalate (column 9, line 1-5). Cetyltrimethylammonium bromide is also a halogen-containing compound, of the type applicants regard as halogen-containing compound, that has deodorizing and antiseptic properties (column 12, lines 18 and 19). Spitzer discloses that the oil-in-water emulsion composition is topically applied as cleansing, conditioning, coating, lubricating agents, personal washing, laundering, dishwashing, shampoos, shaving cream, hair color and rinses (column 12, line 58 to column 13 line 13); Spitzer's oil-in-water emulsion composition is also useful as furniture and shoe cleaners and polish (column 13, lines 14-20). Spitzer's oil-in-water emulsion

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composition may also contain medicaments such as antimicrobial agents (column 13, lines 22-61). Regarding medical device, applicants' specification in paragraph [0091] of the published application defines medical device as a "drug delivery devices" and Spitzer incorporates medicaments such as histamines, sulfa drugs, antibiotics, hormones, vitamins, antimicrobials agents and procaine (column 13, lines 22-53). See also Examples 1-2. The aqueous phase in Spitzer is about 10% to about 75% by weight of the emulsion and by corollary (claim 17), the oil phase would be from about 90% to about 25% by weight of the emulsion and since the density of the emulsion would not be drastically different than the density of water at 1, the weight percent would approximate volume percent. Spitzer meets the limitations of the claims.

Claim Rejections - 35 USC § 103

5. Claims 121 and 131-133 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832).

No arguments were presented against this rejection and the rejection is restated below.

Baker is discussed under 35 USC 102. Baker also discloses that the emulsion is used to inactivate bacteria and bacterial spores on surfaces that come in contact with humans (column 3, lines 40-45). Furthermore, Baker indicates that the emulsions may be combined with edible substances for swallowing (column 5, lines 33-45). Since the emulsion is capable of inactivating bacteria or bacterial spores on any surface that it comes in contact with, it stands to reason, the emulsion may also do the same when it is in contact with edible substance. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use bakers composition to inactivate surfaces that come in contact with human.

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Since food comes in contact with humans, combining the emulsion with edible substance would inactivate bacteria present in the edible substance.

6. Claims 104, 110, 111, 113 and 114 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Homola et al. (US 5,961,958) or Hill (US 5,380,530).

Homola discloses a composition that can be formulated as an oil-in-water micro-emulsion (column 20, lines 22-26); the micro-emulsion comprises surfactants (column 7, line 34; column 9, lines 60-62; column 13, lines 34-64) or halogen containing compounds that are antimicrobial and also surfactants (column 7, lines 7-13; column 11, line 42 to column 12 line 3); the composition is prepared with methanol or ethanol (column 19, line 50); the micro-emulsion containing the halogen compound, surfactant and alcohol can be deposited on dental surfaces can be used to treat teeth (column 4, lines 19-56) or coat tooth picks or dental floss or included in toothpastes (column 4, lines 6-18; columns 5 and 6). Micro-emulsion anticipates the broad emulsion. Thus, Homola' micro-emulsion protects the surface of teeth. In the alternative, micro-emulsion, a form of emulsion containing the antimicrobial halogen containing compounds is applied to dental surfaces, it would be obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Homola in the form of emulsion with the expectation that the emulsion can be effectively deposited on dental surfaces to protect the teeth from microbial assault and treat teeth sensitivity.

Hill discloses oral hygiene formulation that comprises emulsion that contains surfactant (column 10, lines 14-20, 47-55), oil (column 12, lines 36-68; column 17, lines 22-33), therapeutic substances (column 9, lines 54, 66) such as triclosan, cetylpyridinium chloride and

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antibiotics (column 15, line 20 to column 16 line 5). Cetylpyridinium chloride is a halogen-containing compound. The formulation is an emulsion but Hill does not specifically state an oil-in-water emulsion. The emulsion of Hill is used to coat chewing gum, which when chewed releases therapeutic agents to the dental area. Since the composition contains oil and aqueous medium, one of ordinary skill in the art at the time the invention was made is able to prepare an oil-in-water emulsion with the expectation that chewing gums prepared from the oil-in-water emulsion would confer therapeutic effect in the dental area with each chewing.

7. Claims 121 and 131-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832) and Simmons et al. (US 5,405,602).

Baker is discussed under 35 USC 102. Baker also discloses that the emulsion is used to inactivate bacteria and bacterial spores on surfaces that come in contact with humans (column 3, lines 40-45). Furthermore, Baker indicates that the emulsions may be combined with edible substances for swallowing (column 5, lines 33-45). Since the emulsion is capable of inactivating bacteria or bacterial spores on any surface that it comes in contact with, it stands to reason, the emulsion may also do the same when it is in contact with edible substance. Baker does not disclose halogen-containing compound. But, Simmons discloses a composition containing halogen-containing compound that inactivates or kills bacterial spores (column 10, lines 54-59, 60-68; column 11, lines 38, 45-55, 60-65; column 12, lines 13-18 and line 26 to column 13 line 10). Both compositions of Baker and Simmons inactivate or kill bacterial spore.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined composition of Baker and Simmons to form a third composition with the expectation that the third composition would inactivate or kill bacterial

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spores. The idea of combining them flows logically from their having been individually taught in the prior art. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

8. Claims 75 and 96 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

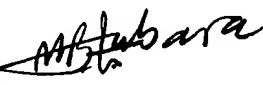
9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara 
Patent Examiner
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